

## **REMARKS**

Entry of the foregoing, and further and favorable reconsideration of the subject application are respectfully requested.

By the present Amendment, claims 1, 8-11, and 51-57 have been canceled without prejudice to or disclaimer of the subject matter recited therein. New claims 58-83 have been added. The subject matter of these new claims corresponds to claims 1-11, 20-28, and 38-44 as originally filed. No new matter has been added.

Applicants note that the election of species requirement mailed in this case on August 24, 2005, and the response thereto filed on September 14, 2005 remain in effect. Current claims 58 and 77 are generic. Accordingly, entry of this Amendment, and consideration of the new claims on the merits is believed to be in order and is respectfully requested, despite the finality of the outstanding Office Action.

### **Interview Summary**

Applicants gratefully acknowledge the courtesy shown to their undersigned representative by the Examiner in the personal interviews held on April 13 and May 11, 2010. In those interviews, the cited art was discussed, as well as the scope of the current claims, and data relating to the claimed invention were presented.

## **Claim Rejections - 35 USC §103**

Claims 8-11, 51-53, 55, 56, and 57 were rejected under 35 USC 103(a) as purportedly obvious over Brown 2003/0003127, in view of Evans 2003/0236573. This rejection, to the extent that it applies to claims 58-83, is respectfully traversed.

The Examiner concedes, at p. 4 of the Official Action, that Brown “fails to teach a device that is completely non-porous when initially implanted or a device that fills the interconnected pores throughout the entire ceramic structure.” Applicants agree with this characterization of Brown.

The Examiner asserts, at p. 4 of the Official Action, that “Brown teaches a zone where the interconnected pores throughout the entire ceramic structure are filled, and a zone where they are not.” Applicants submit that Brown teaches a layered structure, where both layers are porous, and where the layers are interconnected at the interface because the substance of each layer is “infiltrated” into the pores of the adjacent layer, thereby creating “interlocking” layers. See Brown paragraph [0026] and Figure 1.

Brown discloses that these interlocking porous layers represent a critical advance over the prior art. Specifically, Brown discloses, at paragraph [0023],

One of the major weaknesses of the prior art regarding laminated scaffolds is that the layers are not completely integrated and are subject to delamination under in vivo conditions. The present invention solves the problem of delamination by the lyophilization of a porous polymer foam in the presence of a porous ceramic, interlocking the porous polymeric foam with the porous ceramic by way of an interphase zone of porous polymer infiltrated into the porous ceramic. This interphase zone exhibits a microporous polymer foam located within the macropores of a porous ceramic. The interpenetration of the two porous layers creates a strong mechanical junction while simultaneously providing a gradual change in material properties for the purpose of regenerating different tissues or co-culturing different types of cells in intimate contact with one another. The interconnecting pores and channels facilitate the transport of nutrients and/or invasion of cells into the scaffold, facilitating the ingrowth of tissue. This transitional composite structure more closely mimics naturally occurring tissue junctions. The present invention therefore facilitates

cellular organization and the regeneration of tissue junctions with normal morphology and physiology.

It is important to recognize that the Brown discloses a “laminated scaffold” device that includes two porous layers (see, e.g., Figure 1), where the substances that make up the two layers interpenetrate at the interface between the two layers via those pores.

However, the balance of the two layers remains porous.

The Examiner asserts, at p. 4 of the Official Action, that Evans discloses

that it may be desirable to have non-porous portions of the implant, and further, specifically, an implant which is initially a non-porous resorbable macrostructure, where the pores of the device are filled, with a microstructure that degrades more rapidly, so that the porosity is then revealed, for the purpose of controlling the porosity of the device along a timeline that is related to the various rates of in vivo degradation.

The implant referred to by the Examiner is shown in Figures 2A and 2B, and described at paragraphs [0126]-[0132] of the specification. Paragraph [0131] includes the language cited by the Examiner at p. 4 of the Official Action. This implant is not a “laminated scaffold” as disclosed by Brown. Instead, the implant is described by Evans as being “formed of dense polymer (e.g. collagen) foam with long native collagen fiber reinforcement.” *Paragraph [0126].*

With respect to the section of the specification quoted by the Examiner, Evans does not define what materials may be used to form the “microstructure” which fills the pores of the “macrostructure.” However, Evans does disclose that the implant “may contain particles of a calcium derivative such as, but not limited to, calcium sulfate or hydroxyapatite throughout the implant to enhance the healing properties.” *Paragraph [0126].*

At p. 5 of the Official Action, the Examiner argues that it would have been obvious, at the time the presently claimed invention was made,

to modify the two-material ceramic polymer scaffold structure of Brown in view of Evans, to have non-porous portions of the Brown device as well,

and further, that it may be desirable to have an implant which is comprised of two materials, only one of which is macroporous, which is then filled by a secondary material, so that when the secondary material is degraded, the porosity is then revealed.

Applicants respectfully disagree. First, as noted above, the implant of Brown is intentionally porous, except at the interface between the two layers, where the materials of each layer “interpenetrate” through the pores. This allows the patient’s cells to penetrate the layers (see paragraph [0064]). It would defeat the purpose of Brown to fill the pores of the Brown implant.

Second, filling the pores of the Brown implant would require introducing at least a third component into the implant in order to fill the pores in the implant. The presently claimed invention does not exclude the possibility of additional materials. However, in the presently claimed invention, the pores in the first (porous) component are filled by the second component.

Third, one of ordinary skill in the art would not be motivated to modify the layered scaffold of Brown in view of the Evans implant. This is true at least because Evans does not provide guidance that would allow one of ordinary skill to make and use a porous implant in which a “microstructure” fills the “macrostructure” of the implant, because Evans does not define suitable materials that could be used to create such a “microstructure.” One of ordinary skill in the art would thus be left to experiment in order to determine what materials might be used to form the “microstructure.”

As noted above, Evans does disclose that the implant may contain “a calcium derivative, such as ...calcium sulfate or hydroxyapatite.” However, as shown in the attached publication by Fracs et al.<sup>1</sup>, the use of implants constructed from a polymer blended with a calcium salt in patients undergoing knee reconstruction did not promote

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<sup>1</sup> Fracs, J.P.R., et al. (2010) Randomised controlled trial of osteoconductive fixation screws for ACL reconstruction. A comparison of the Calaxo and the Milagro screw. 12 month results. *American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans 2010.*

bone healing, and in fact cause complications, including increased tunnel volume and the formation of tibial cysts. One of ordinary skill who attempted to create an implant containing a calcium salt, as disclosed by Evans, would not succeed in creating a medically useful implant. The presently claimed device represents an effort to solve the problems associated with these prior implants, a solution which was not recognized by either Brown or Evans. Accordingly, the presently claimed device is not *prima facie* obvious over Brown in view of Evans.

### SUMMARY

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions concerning this paper, or the application in general, the Examiner is respectfully urged to contact Applicants' undersigned representative so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047, Order No. 7300052001.

Respectfully submitted,  
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